

**REMARKS**

Claims 1-20 stand cancelled from a previous response and claims 25, 28 and 31 are newly cancelled. Claims 21, 26-27, 29-30 and 32 have been amended. No new matter is presented by virtue of the within amendments; support therefore can be found throughout the specification and claims of the application. For instance, support for the amendments to independent claims 21, 27 and 30 is found in former claim 25, original claims 8 and 9, and in the specification, e.g., at page 11, line 12, to page 12, line 15.

As an initial matter, it is believed the amendments may be properly entered at this time, i.e. after final rejection, pursuant to 37 CFR §1.116, because the amendments do not require a new search or raise any new issues, and they reduce issues for appeal. Indeed, it is respectfully submitted that the within amendments place the application in condition for allowance. Thus, entry of the amendments at this time is earnestly solicited.

**Rejections under 35 USC §112, 1<sup>st</sup> paragraph**

The specification is objected to under 35 USC §112, 1<sup>st</sup> paragraph, as allegedly failing to provide an adequate written description of the invention and failing to provide an enabling disclosure (Office Action at page 2).

Claims 21-32 stand rejected under 35 USC §112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the written description requirement for reasons similar to those already made of record (Office Action at pages 2-3).

Claims 27-32 are further rejected under 35 USC §112, 1<sup>st</sup> paragraph, as allegedly failing to comply with the enablement requirement (Office Action at page 4).

The Office Action expressly acknowledges that the specification sufficiently describes and enables a competitive assay with a sample solution for determining phosphatidylinositol-3,4-bisphosphate in a sample solution by comparison to a marker

measured with standard solutions (see e.g., page 15). However, the position is taken that the specification does not reasonably provide enablement for the presently claimed invention where merely a test sample is used and comparisons to blanks and some lesser amount are made.

Without acquiescing to the grounds for the rejection, independent claims 21, 27 and 30 have been amended to further define and clarify the monoclonal antibody to be used in the methods of the invention. In particular, the amended claims recite a specific antibody which has been structurally defined by amino acid sequences of heavy and light chain variable regions.

Further, per the Examiner's suggestion, independent claims 27 and 30 have been amended to recite (i) "standard solution" rather than "standard solution that does not contain the PI-3,4-P2, and also (ii) "test sample solution" rather than "test sample".

Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, 1<sup>st</sup> paragraph, are requested.

Rejections under 35 USC §112, 2<sup>nd</sup> paragraph

Claims 21-32 stand rejected under 35 USC §112, 2<sup>nd</sup> paragraph, as allegedly being indefinite. Various informalities are noted as grounds for the rejection (Office Action at page 5).

The rejection is believed to be obviated by the within amendments. For instance, a typographical error in claim 21 and certain terms lacking antecedent basis throughout the claims have now been corrected.

Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, 2<sup>nd</sup> paragraph, are requested.

In view of the amendments and remarks, Applicant believes the pending application is in condition for allowance.

**PETITION FOR EXTENSION AND FEE AUTHORIZATION**

Applicant requests a three month extension for filing the within response. Additionally, a Notice of Appeal is being filed concurrently herewith to maintain pendency of the application pending the Examiner's consideration of the response. The Commissioner is authorized to charge the fees for the extension and the Notice of Appeal, and any other fees associated with this submission to our Deposit Account, No. 04-1105, Reference 49618DIV(71965). Any overpayment should be credited to said Deposit Account.

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Respectfully submitted,

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